REMARKS

Claims 1, 5-7, 12-14, 18-21, 25, 28-30, 36-37 and 48 were previously pending in this application. Claims 121, 122, 125 and 126 have been withdrawn. Claim 67 has been amended to recite that the lower limit on the length of the nucleic acid is 12 nucleotides. Support for the amendment can be found at least on page 20, lines 4-6 of the specification as filed. No new matter has been added.

The Examiner indicated on page 3, paragraph 3, that claim 118 was rejoined and newly added claim 124 is included in the elected group of claims. However, in paragraph 4 on page 3, the Examiner indicated that claim 118, among others, was withdrawn as not elected. In view of this discrepancy, Applicant has assumed for the purposes of this response that claim 118 has been rejoined and not withdrawn, and therefore is presently pending.

Objection to the Specification

The Examiner objected to the specification for two reasons. First, the Examiner identified hyperlink text in the specification on page 84. Applicant has amended that paragraph of the specification to remove the hyperlink text. Applicant also has searched the specification for additional hyperlink text, and as a result has amended a paragraph on page 18 to remove the hyperlinks listed therein.

Second, the Examiner objected to the specification on the basis that the specification incorporated by reference without specifying the materials sought to be incorporated. Applicant respectfully traverses the rejection.

The Examiner cites a passage from Advanced Display Systems Inc. v. Kent State University, 212 F.3d 1272, 1281, 54 USPQ2d 1673, 1679 (Fed. Cir. 2000). Applicant respectfully disagrees that this case is on point as support for the Examiner's rejection. In the Advance Display Systems case, the issue was whether a prior art document asserted as anticipatory of a claimed invention described every element of the claimed invention. It is settled law that anticipation requires that the four corners of a single, prior art document describe every element of the claimed invention. That issue is not pertinent in the instant case, because the instant application is not being asserted as an anticipatory reference against another application.

Moreover, the context of references cited in the application provide the incorporation with any requisite specificity, as would be recognized by one of ordinary skill in the art. For example, at page 16, beginning at line 19, the specification recites: "Nucleic acid hybridization parameters may be found in references which compile such methods, e.g. *Molecular Cloning: A Laboratory Manual*, J. Sambrook, et al., eds., Second Edition, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York, 1989, or *Current Protocols in Molecular Biology*, F.M. Ausubel, et al., eds., John Wiley & Sons, Inc., New York." These references clearly are incorporated by reference for the nucleic acid hybridization parameters."

Further, in addition to the passage cited by the Examiner, Applicant incorporated by reference specific references in several other places in the specification. These specific incorporation clearly establish the basis on which the reference is incorporated. For example, on page 57, beginning at line 23, the specification recites: "Total RNA was then isolated from the samples, using the guanidium thiocyanate method of Chirgwin, et al., *Biochemistry* 18: 5294-5299 (1979), incorporated by reference." Similarly, on page 58, beginning at line 16, the specification recites: "The method of Sahin et al., *Proc. Natl. Acad. Sci. USA* 92:11810-11813 (1995), and U.S. Patent No. 5,698,396, both of which are incorporated by reference, was used, with some modifications. Specifically...."

In view of the distinction between the cited case law and the present situation, and further in view of the additional specificity provided in the application, Applicant respectfully requests withdrawal of the objections to the specification.

Rejection Under 35 U.S.C. § 112

The Examiner rejected claim 124 under 35 U.S.C. §112, first paragraph, as lacking an adequate written description. Applicant respectfully traverses the rejection.

The Examiner indicated that the specification did not contain an adequate written description "of which fragments of SEQ ID NO:681 actually encode any cancer associated antigen precursor." Office Action at page 4, paragraph 8. Applicant respectfully disagrees.

Claim 124 does not recite a fragment of SEQ ID NO:681 (that is the recitation of claim 64). It recites isolated nucleic acid molecules having a specific nucleotide sequence (SEQ ID

NO:681), nucleotide sequences that hybridize under stringent conditions to SEQ ID NO:681 and degenerates and complements thereof. All of these elements of the claim find ample written description, which is certainly adequate to convey to the person of skill in the art that Applicant was in possession of the claimed invention as required by the law. Vas-Cath v. Mahurkar, 35 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991) (written description requirement requires that the claimed invention must be described clearly enough to allow one of ordinary skill in the art to recognize that the inventors invented the claimed invention).

In view of the foregoing, Applicant respectfully requests withdrawal of the rejection for lack of an adequate written description.

The Examiner also suggested that the specification does not provide an adequate written description of how to use the cancer antigen precursors. Office Action at page 5, paragraph 9. Applicant respectfully disagrees.

The requirement for an adequate written description, as described above, is that it must convey to one of ordinary skill in the art that an applicant invented that which is claimed. Vas-Cath v. Mahurkar.

Applicant has done just that in the instant application. There are several passages in the application that describe exactly how to use the cancer antigen precursors (polypeptides). Principally the recited uses involve using the polypeptides for therapeutic purposes, e.g., vaccination. Other described uses include generation of antibodies against the cancer antigen precursors, as part of diagnostic assays, etc. These uses are very well known to persons of ordinary skill in the art and their recitation is adequate to convey to such persons that Applicant was in possession of the claimed invention and uses of the claimed invention. Specific examples of the description include the following.

Beginning at page 18, line 2: "Encoded polypeptides (e.g., proteins), peptides and antisera thereto are also preferred for diagnosis." Several occurrences of this recitation, stated as relating to particular sets of cancer-associated genes (breast, renal, etc.), are present in this part of the specification.

Beginning at page 27, line 30: "The invention also provides isolated polypeptides (including whole proteins and partial proteins) encoded by the foregoing cancer associated

antigen nucleic acids. Such polypeptides are useful, for example, alone or as fusion proteins to generate antibodies, as components of an immunoassay or diagnostic assay or as therapeutics."

Beginning at page 32, line 11: "The isolation and identification of cancer associated antigen genes also makes it possible for the artisan to diagnose a disorder characterized by expression of cancer associated antigens. These methods involve determining expression of one or more cancer associated antigen nucleic acids, and/or encoded cancer associated antigen polypeptides and/or peptides derived therefrom."

Beginning at page 39, line 14: "A similar effect (CTL stimulation) can be achieved by combining the cancer associated antigen or a stimulatory fragment thereof with an adjuvant to facilitate incorporation into antigen presenting cells *in vivo*. The breast cancer associated antigen polypeptide is processed to yield the peptide partner of the HLA molecule.... Generally, subjects can receive an intradermal injection of an effective amount of the cancer associated antigen. Initial doses can be followed by booster doses, following immunization protocols standard in the art."

Beginning at page 40, line 11: "As part of the immunization compositions, one or more cancer associated antigens or stimulatory fragments thereof are administered with one or more adjuvants to induce an immune response or to increase an immune response. "

Beginning at page 42, line 25: "A cancer associated antigen polypeptide, or a fragment thereof, also can be used to isolate their native binding partners."

Beginning at page 43, line 12: "The invention also contemplates delivery of nucleic acids, polypeptides or peptides for vaccination. Delivery of polypeptides and peptides can be accomplished according to standard vaccination protocols which are well known in the art."

Beginning at page 46, line 17: "The compositions of the invention are administered in effective amounts. An "effective amount" is that amount of a cancer associated antigen composition that alone, or together with further doses, produces the desired response, e.g. increases an immune response to the cancer associated antigen."

In view of the foregoing, Applicants assert that the claimed invention is adequately described in the specification. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 112, first paragraph.

Rejection Under 35 U.S.C. § 102

The Examiner has rejected claims 67 and 124 under 35 U.S.C. §102(b) as anticipated by Brennan (US patent 5,474,796).

According to the Examiner, the Brennan patent discloses an array of isolated oligonucleotides that comprise all possible 10-mers, and that this disclosure "fairly encompasses all 10-mers now claimed by applicant." Office Action at page 5, paragraph 13. The Examiner concludes that this disclosure by Brennan anticipated the claimed invention.

Applicant disagrees with the Examiner regarding the teaching of Brennan because Brennan explicitly recites exactly one sequence of 10 nucleotides or more, SEQ ID NO:1. While there is a brief mention at col. 9, lines 53-55 that "the total array represents every possible permutation of the 10-mer oligonucleotide," this by itself is not a disclosure of each of the 10 nucleotide sequences that is sufficient to provide a basis for anticipation.

In contrast, Applicant provides a longer sequence and teaches that fragments can be obtained. These fragments have a definite sequence, based on SEQ ID NO:681; they are not hypothetical sequences as those obliquely suggested by Brennan. Because Brennan utterly lacks specificity (except for its single disclosed 10-mer sequence, SEQ ID NO: 1), it is not an enabling reference that is effective to anticipate Applicant's claims.

Moreover, there is nothing in Brennan that even remotely suggests the invention claimed in claim 124, i.e., SEQ ID NO:681, nucleotide sequences that hybridize under stringent conditions to SEQ ID NO:681 and degenerates and complements thereof.

Although Applicant respectfully disagrees with the Examiner's conclusions based on Brennan, in order to facilitate allowance of the claims Applicant has amended claim 67 and respectfully requests reconsideration. Claim 67 as now amended recites that the claimed nucleic acid comprises a fragment of SEQ ID NO:681 of at least 12 nucleotides.

Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 102.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
Old et al., Applicant

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